4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1240]

Draft Guidance for Industry and Food and Drug Administration Staff; Submissions for Postapproval Modifications to a Combination Product Approved Under Certain Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." This draft guidance intends to provide the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product that is approved under one marketing application, i.e., a biologics license application (BLA), a new drug application (NDA), or a device premarket approval application (PMA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32,

rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your request. The draft guidance may also be obtained by mail by calling the Office of Combination Products at 301-796-8930. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." This document provides guidance to industry and FDA staff on the underlying principles to determine the type of marketing submission that may be required for postapproval changes to a combination product, as defined in 21 CFR 3.2(e), that is approved under one marketing application, i.e., a BLA, an NDA, or a device PMA.

The regulatory standards for when to provide a postmarket submission for a change to an approved, stand-alone drug, device, or biological product or its manufacturing process are described in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 505, 506A, and 515 of the FD&C Act), the Public Health Service Act (PHS Act) (section 351 of the PHS Act), and FDA's associated regulations (21 CFR 314.70, 601.12, and 814.39). As a general matter, these provisions set forth similar criteria for when a submission for a changed article is required, but do not expressly address submissions for changes to an approved combination product.

This draft guidance intends to provide clarity in the postapproval change requirements and consistency in the type of postmarket submission to provide for a change to a combination product approved under one marketing application (BLA, NDA, or PMA). In particular, the draft guidance document provides tables that may be helpful in determining what type of submission to provide for a postmarket change to a constituent part of a combination product where the regulatory identity of the modified constituent part differs from the application type under which the combination product is approved.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Submissions for Postapproval Modifications to a Combination Product Approved Under a BLA, NDA, or PMA." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments to http://www.regulations.gov or written comments regarding this document to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 for NDAs have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 814, subpart B for PMAs have been approved under OMB control number 0910-0231.

Dated: January 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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